UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,752	04/16/2001	Jose Halperin	H0498/7137(ERG)	5292

7590 06/13/2003

Edward R. Gates
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Ave
Boston, MA 02210

EXAMINER
DECLOUX, AMY M

ART UNIT	PAPER NUMBER
1644	14

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/835,752	HALPERIN, JOSE	
	Examiner	Art Unit	
	Amy M. DeCloux	1644	

-- The MAILING DATE of this communication appears on the c ver sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any *earned patent term adjustment.* See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-32 and 34-41* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 5-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,9-32 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's amendment (Paper No. 13) and the declaration (Paper No. 12), both filed 3-24-03, are acknowledged and have been entered.

Drawings

The corrected or substitute drawings were received on 3-24-03 (Paper No. 11). These drawings are acceptable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

MAINTAINED IN PART Claims 4 and 9-40 and newly added claim 41, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining regression, progression or onset of diabetes comprising obtaining a level of the amount of K41-glycated CD59 from urine obtained from a subject and comparing the level to a control as a determination of regression, progression or onset of the condition, using an agent that comprises antibodies that bind glycated and nonglycated CD59, does not reasonably provide enablement for a method for determining regression, progression or onset of diabetes comprising obtaining a level of the amount of K41-glycated CD59 from **ANY** sample obtained from a subject and comparing the level to a control as a determination of regression, progression or onset of the condition, using **ANY** antigen or antigen binding fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Response to Arguments

In view of Applicant's amendment and declaration filed 3-24-03, the 112 first paragraph rejection is overcome in part. Specifically, the newly added limitation of a diabetic condition that is being treated by the method recited in base claim 4 overcomes the scope rejection regarding enablement for any condition other than diabetes. Also the newly added limitation of an antibody or antigen-binding fragment thereof as an agent that is encompassed by the method recited in base claim 4 overcomes the scope rejection regarding enablement for any agent other than an antibody or antigen-binding fragment thereof.

However, Applicant's declaration does not overcome the scope rejection regarding the enablement of the recited method comprising any sample because the declaration shows that the recited method is enabling for human plasma, urine or tissue, but not for any non-human plasma

or urine or tissue as evidenced by a post filing date reference authored in part by the inventor (Acosta et al. PNAS 97(10):5450-5455). Acosta et al teaches that a preferential glycation motif comprising K41 is present in human CD59, but not in CD59 of other species. Since said glycation motif is not present in the CD59 of other species, Applicant is only enabled for the recited method comprising for human plasma, urine or tissue.

Furthermore, neither the specification nor said declaration discloses that the recited method encompasses any antibody or antigen-binding fragment other than those that bind CD59. Since the recited method comprises obtaining a level of the amount of K41-glycated CD59, it would require undue experimentation to predict which antibodies other than an antibody or an antigen binding fragment thereof directed to CD59, would be effective in the recited method without further guidance from the instant specification.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner, 1644
June 3, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600